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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,280

03/04/2004

Michael R. Bowman

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11/29/2007

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/792,280

Applicant(s)

BOWMAN ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9,11 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,8,10,12,13 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2007 has been entered.

Election/Restrictions

2. Applicants have responded to the withdrawal of claim 23 by stating that elected species C, lysine, is readable upon claim 23. The Examiner agrees and claim 23 is rejoined with the elected claims.

Status of the Claims

Claims 1, 4, 6, 8, 10, 12, 13 and 21-24 are under examination.

Claims 2, 3, and 14-20 are cancelled.

Claims 5, 7, 9, 11, and 25 are withdrawn as being drawn to a non-elected group.

Information Disclosure Statement

3. The ISR listed on the information disclosure statement filed April 15, 2005 has been considered.

Specification

4. The use of the trademarks GENECHIP and AFFYMETRIX has been noted in this application. See page 9, for example. It should be capitalized wherever they appear and be accompanied by the generic terminology. Please capitalize all trademarks.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 4, 6, 12, 13 and 21 - 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (US 2004/0057926) as supported by its priority document, Provisional Application 60/363366 and in light of Jeffery (Am. J. Respir. Crit. Care Med. (2001) Volume 164, pages S28-S38).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with a chronic obstructive pulmonary disease wherein the agent inhibits the activity of CAT2 in a tissue affected by the disease.

Regarding claims 21-24, Ochoa et al. teach in US #2004/0057926 administering an therapeutically effective amount of lysine (Abstract; Pages 1-2, paragraph 0013; Page 2, paragraph 0016) which inhibits a component of the arginine metabolic pathway such as a cationic amino acid transporter 2 (Page 2, paragraph 0016) for treating a respiratory disease such as chronic obstructive pulmonary disease (Page 6, paragraph 0063) to a mammal (page 1, paragraph 0013).

In the Provisional Application 60/363366, Ochoa et al. teach administering an agent to modulate the level of arginine in a tissue or bodily system to regulate an immune response (page 3, page 15), such as lysine, which inhibits the activity of CAT2 a component of the arginine metabolic pathway, (page 7), for treating patients (i.e. humans) (page 4). Ochoa et al. also teaches that diseases that result from an alteration in the management of l-arginine levels include chronic obstructive pulmonary disease (page 2), thereby providing support for the explicit teachings of '926.

Although, Ochoa et al. does not specifically mention chronic airway remodeling, Jeffery teaches that asthma and COPD are accompanied with structural changes known as chronic airway remodeling (page S28; page S29, right column). Thus, a method of providing lysine, which binds to CAT2, to a mammal with asthma or COPD is necessarily also a method of providing lysine to a mammal with chronic airway remodeling as in claims 1, 4, 6, 12 and 13.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use Ochoa et al.'s method to treat chronic obstructive pulmonary disease. While Ochoa et al.'s provisional application does not explicitly teach administering lysine to a patient with chronic obstructive pulmonary disease, Ochoa et al. teaches that chronic obstructive pulmonary disease results from altered levels of L-arginine (page 2). Ochoa et al. et al teaches that levels of L-arginine may be modulated to treat patients using agents such as lysine (page 7). Thus, one of ordinary skill in the art seeking to treat chronic obstructive pulmonary disease, in the presence or absence of chronic airway remodeling, would have been motivated to use the agents taught by Ochoa et al.

Response to Arguments

7. Ochoa et al. was previously used in a rejection under 35 U.S.C. §102. Applicants presented arguments that Ochoa et al. did not explicitly anticipate administering an agent to a mammal that has chronic obstructive pulmonary disease, in the provisional application. The Applicants' arguments that the provisional application, which is relied upon for a priority date prior to the filing date of the instant application, is

not anticipatory are persuasive. However, as explained above, the instant claims are still unpatentable as being obvious over Ochoa et al., wherein the provisional application does suggest the instantly claimed invention.

8. Claims '1, 4, 6, 8, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al. (US 2003/0166562) in light of Jeffery (Am. J. Respir. Crit. Care Med. (2001) Volume 164, pages S28-S38).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with chronic airway remodeling wherein the agent inhibits an activity or expression of a component of an arginine metabolic pathway that is not NOS.

Rothenberg et al. teach a method that includes administering a therapeutically effective amount of an agent to a mammal with asthma which inhibits CAT2 or the gene encoding for CAT2 (page 2, paragraphs 0016-0019); wherein one possible agent is capable of binding to a polynucleotide encoding the component by an antisense mechanism (page 12, paragraph 0069 - page 13, paragraph 0071); wherein another possible agent is lysine or a cationic polypeptide for inhibiting CAT2 (page 13, paragraph 0075, page 2, paragraph 13); where the mammal is human (page 2, paragraph 0016; page 4, paragraph 0041). Jeffery teaches that asthma and COPD are accompanied with structural changes known as chronic airway remodeling (page S28; page S29, right column). Thus, it would have been obvious to one of ordinary skill in

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the art that a method of providing an agent to a mammal with asthma would also be providing an agent to a mammal with chronic airway remodeling.

This rejection is necessitated by amendment.

Response to Arguments

9. Rothenberg et al. was previously used in a rejection under 35 U.S.C. §102. Applicants presented arguments that Rothenberg et al. did not explicitly anticipate administering an agent to a mammal that has chronic airway remodeling, which the Examiner found persuasive. However, as explained above, the instant claims are still unpatentable as being obvious over Rothenberg et al. in light of Jeffery.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al. (US 2003/0166562) in light of Jeffery (Am. J. Respir. Crit. Care Med. (2001) Volume 164, pages S28-S38) as applied to claims 1, 4, 6, 8, 12 and 13 above, and further in view of Hannon (Nature (2002) volume 418, pages 244-251).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with chronic airway remodeling where an agent such as siRNA inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase.

Rothenberg et al. in light of Jeffery is applied as above.

However Rothenberg et al. do not specifically teach using siRNA.

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Regarding claim 10, Hannon teaches that siRNA may be synthesized to target and silence genes of interest (page 245; page 250).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Rothenberg et al. in light of Jeffrey et al. with Hannon to administer siRNA for the purpose of inhibiting the production of CAT2. Rothenberg et al. teach that the inhibition of CAT2 expression via antisense mechanisms is desirable to treat asthma (page 14, paragraphs 0082 and 0091; page 16, paragraph 0012). However, Hannon teaches that siRNA is a much more potent inhibitor of gene expression than sense or antisense RNAs (page 244, right column). Thus one of ordinary skill in the art seeking to inhibit CAT2 mRNA would be motivated to use siRNA for the increased potency of siRNA over sense or antisense RNAs.

Response to Arguments

11. Applicants have responded to using the combination of Rothenberg et al. and Hannon by stating that neither reference teach administering an agent to a mammal that has chronic airway remodeling. However, as explained above, the instant claims are still unpatentable as being obvious over Rothenberg et al. in light of Jeffery in view of Hannon.

Withdrawn Rejections

12. Applicant's arguments and amendments, filed July 12, 2007, with respect to the rejection of claims 1, 4, 6, 8, 12-14, 21, 22, 24 under 35 U.S.C. §102 are moot in view of the new rejections set forth above.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Marjorie A. Moran/
SPE, AU 1631
11/16/2007